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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,122	CLIFFORD ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,8-14,23,25,27,30-36 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,8-14,23,25,27,30-36 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1, 3, 4, 6-14, 16, 23, and 25-38 have been considered but are moot in view of the new ground(s) of rejection.

It is noted to the applicant that the examiner is interpreting the word "corrugations" by its broadest definition being "to form or to shape into wrinkles or folds or into alternating ridges and grooves". The references applied below have alternating ridges and grooves. The references below have corrugations on the sleeve *surface*, which reads on the claims, since applicant has not claimed the sleeve to have a *single or uniform thickness*, wherein the entire *sleeve wall thickness is corrugated*.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 8-14, 23, 25, 27, 30-36, and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 25 recite, "wherein the internal sleeve and the outer sleeve are fixed to one another such that relative motion between the internal sleeve and the outer sleeve is substantially eliminated". Such subject matter was not found in the specification, and seems to only be an attempt to amend to try to teach away from one of the

applied references. Within the claims 1 and 25, the applicant has claimed a connection point, which is merely contact between a corrugation on one sleeve, made with the other sleeve, which does not necessarily eliminated motion, and elimination of motion is not disclosed in the specification (it is also noted to the applicant, that the Schlar reference, shows the exact structure claimed, contact between a corrugation on the internal sleeve, with the outer sleeve, therefore, inherently will perform in the same manner) and is being treated as new matter. Claims 4, 8-14, 23, 27, 30-36, and 38 depend upon claims 1 and 25 and inherit all problems with the claim.

Claims 8, 9, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No disclosure was found in the specification of two corrugated loops or sheets. The applicant has disclosed an internal sleeve and an outer sleeve, the internal sleeve being corrugated, however, the *outer sleeve is never shown or disclosed to also be corrugated.*

Claim Rejections - 35 USC § 101

Claims 1, 14, 25, and 36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The applicant has positively claimed a portion of the body in each of the above claims, which is non-statutory subject matter. Claims 1 and 25 each recite, "wherein the implant bears a load between the first one of the vertebrae". It is suggested to change to --wherein the implant is *adapted* to bear a load--. Also, in claims 1 and 25, the applicant has recited, "corrugations extending radially outward around an axis extending from the first one of the vertebrae to the second one of the vertebrae". It is unclear to the examiner

whether the applicant is claiming the *corrugations* extend between the two vertebrae, or the *axis* extends between the vertebrae. If the applicant is claiming the corrugations extending between the vertebrae, the vertebrae has been positively claimed and should be changed to extend from the two ends of the sleeve or implant.

Referring to claims 14 and 36, the applicant has recited, "being secured around a bone", and in doing so, has positively claimed a portion of the body, a bone. Not only has the applicant positively claimed the body, they have altered the claim from an intervertebral implant, to a device that surrounds a bone, which is improper since they are entirely different embodiments that aren't even useable together.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 32, 33, 35, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Studer et al. (US 6,193,756 B1). Studer discloses an intervertebral implant (fig.1, 5, 2, 3) comprising an internal sleeve (2) being foraminous (openings 24) and having corrugations (grooves 8, 8a, 8b, 8c, and surfaces/ridges protruding from these grooves), and an outer sleeve (1) being foraminous (openings 24), the two sleeves disposed in a concentric orientation to form the implant (fig.1, 2, 3), wherein corrugations of the internal sleeve meet the outer sleeve (fig.1, 4; protrusions 7 on outer sleeve touch grooves 8 on inner sleeve), forming a connection point,

and wherein the implant has two open ends and is formed of titanium (col.2, lines 55-56). Studer discloses the sleeves (1, 2) to have a circular cross section (see figs.) and which may be filled with bone material (col.2, lines 62-65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4, 10, 11, 13, 23, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Studer et al. (US 6,193,756 B1). Studer discloses an intervertebral implant (fig.1, 5, 2, 3) comprising an internal sleeve (2) being foraminous (openings 24) and having corrugations (grooves 8, 8a, 8b, 8c, and surfaces/ridges protruding from these grooves), and an outer sleeve (1) being foraminous (openings 24), the two sleeves disposed in a concentric orientation to form the implant (fig.1, 2, 3), wherein corrugations of the internal sleeve meet the outer sleeve (fig.1, 4; protrusions 7 on outer sleeve touch grooves 8 on inner sleeve), forming a connection point, and wherein the implant has two open ends. Studer discloses a biocompatible material to have a thickness (as seen in the figures), however is silent to mention any specific dimensions. It would have been an obvious matter of design choice to have a thickness of 0.5-3.0mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Studer discloses the sleeves to be formed of titanium (col.2, lines 55-56). Studer discloses the sleeves (1, 2) to have a circular cross section (see figs.) and which may be filled with bone material (col.2, lines 62-65).

Claims 1, 4, 8-11, 13, 23, 25, 27, 30-33, 35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US 6,616,695 B1). Crozet discloses an intervertebral implant (4+6 or 102) comprising an internal sleeve (4, 104) being foraminous (12, 138) and having corrugations (threads), and an outer sleeve (6, 106) being foraminous (14, 138), the two sleeves disposed in a concentric orientation to form the implant (see figs.), wherein corrugations (threads) of the internal sleeve (4, 104) meet the outer sleeve (6, 106), forming a connection point, and wherein the implant has two open ends (embodiment in fig.1-3 shows two sleeves with two open ends (the end caps are separate parts and need not be present) and embodiment in fig.4-6 has two open ends). Crozet discloses the implant to be a load bearing biocompatible material (used in between the vertebrae) and having a thickness (seen in figs), however is silent to mention any specific materials, or dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant out of titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. It also would have been an obvious matter of design choice to have a thickness of between about 0.5mm and 3.0mm, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Crozet discloses both sleeves (4, 6, 104, 106) to be corrugated (threads on both parts) and foraminous (openings 12, 14, 138). Crozet has shown the sleeves to have a circular shape. Crozet discloses the sleeves to surround bone material (col.4, lines 53-60).

Claims 1, 4, 10-12, 14, 25, 27, 32-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schar et al. (USPN 6,176,881 B1, cited in previous office action). Schar discloses an intervertebral implant (col.1, lines 4-5) comprising an internal sleeve (1) being foraminous (openings 30) and having corrugations (ridges and groove 5), and an outer sleeve (2) being foraminous (30), the two sleeves disposed in a concentric orientation to form the implant (see figs.), wherein corrugations (5) of the internal sleeve (1) meet the outer sleeve (2), forming a connection point (see fig.3, where corrugations 5 meet and contact the inner surface of the outer sleeve), and wherein the implant has two open ends (sleeves 1, 2 are hollow sleeves with open ends; the caps shown are separate pieces and may not be used). Schar discloses the implant to be a load bearing biocompatible material and (rigid material, col.1, lines 34-35) having a thickness (fig.1, 6, 7), however is silent to mention any specific materials, or dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant out of titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. *In re Leshin*, 125 USPQ 416. It also would have been an obvious matter of design choice to have a thickness of between about 0.5mm and 3.0mm, since such a modification would have involved a mere change in the size of a component. A change in size is

generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Schar discloses the implant having a substantially circular shape (fig.6) or elliptical (col.1, lines 46-49). Schar discloses an implant comprised of an intersecting network of landed regions (sleeve material, 1) that define a plurality of openings (30) in the network, wherein the openings (30) are dispersed among the landed regions (fig.1). Schar discloses the sleeve (1) to have a plurality of openings (30, or openings seen in fig.6 where 25 and 26 protrude therethrough), the implant having a cerclage (24 +25+26) passing through the openings and secured to the sleeve (see fig.6).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER